Press Release

GenSight Biologics Reports Cash Position as of March 31, 2023, and Provides Business Update

- EMA oral presentation held on April 19 with KOLs; decision to withdraw application and engage with EMA to quickly agree on a path forward
- Validation campaign manufacturing restart confirmed in May 2023, with results expected in Q3 2023; training and preparatory work progressing as planned
- Current cash runway to June 2023; advanced discussions on financing and strategic options including M&A ongoing

Paris, France, Thursday April 20, 2023, 7:00 pm CEST – GenSight Biologics (Euronext: SIGHT, ISIN: FR0013183985, PEA-PME eligible), a biopharma company focused on developing and commercializing innovative gene therapies for retinal neurodegenerative diseases and central nervous system disorders, today reported its cash position as of March 31, 2023, and provided a business update.

Regulatory Pathway of LUMEVOQ®

In March 2023, as planned, GenSight submitted responses to the D180 questions from the European Medicines Agency (EMA). The Committee for Advanced Therapies (CAT) of the EMA, in charge of assessing LUMEVOQ®, had remaining objections that were discussed in an oral presentation held yesterday, April 19. GenSight regulatory and clinical executives presented to members of the CAT and were supported by renowned LHON expert and Principal Investigator of REFLECT, **Patrick Yu-Wai-Man, MD, PhD** (University of Cambridge, United Kingdom) and distinguished blindness and vision restoration expert and co-founder of GenSight Biologics, **José-Alain Sahel, MD** (University of Pittsburgh School of Medicine, United-States).

Based on interactions with the EMA CAT indicating that the data provided thus far would not be sufficient to support a positive opinion of the marketing authorization of LUMEVOQ® by EMA, and as announced earlier today, GenSight decided to withdraw its application ahead of a final opinion by the CAT. This decision enables the Company to discuss the best possible path forward for LUMEVOQ® with the EMA in the coming weeks, aiming at submitting a new application addressing remaining objections as soon as possible, in Europe and other countries. The Company is exploring options including generating new clinical data.

GenSight management team hosted a live webcast earlier today that is available for replay, in English with a French translation, using this link: https://bit.ly/3LcxrMD

In parallel, GenSight continues to interact with the U.S. Food and Drug Administration (FDA) to secure a regulatory pathway in the United States and the design of a possible additional Phase III clinical trial.

Manufacturing of LUMEVOQ®

Due to the occurrence of an operational issue at the Company's manufacturing partner in the US, the production of a GMP batch of LUMEVOQ® was terminated in March 2023. The precise root cause was confirmed in April and presented during a dedicated webcast. To prevent the reoccurrence of such an operational issue and secure a successful outcome, GenSight agreed with its manufacturing partner to jointly involve their engineering team and GenSight's own experts (including a person-in-plant at all times) real time in the conduct of the upcoming validation campaign.

GenSight expects to initiate the validation campaign in May 2023, with results expected in Q3 2023, as previously stated. The three PPQ batches could be released for human use by the end of the year.

Cash position as of March 31, 2023

GenSight Biologics' cash and cash equivalents totalled €8.5 million as of March 31, 2023, compared to €10.6 million as of December 31, 2022.

The operating cash burn in the first quarter of 2023 mainly reflected the final pharmaceutical development steps for LUMEVOQ® (lenadogene nolparvovec) to support the Marketing Authorisation Application under review by the European Medicines Agency (EMA). These were mainly preparatory activities to ensure manufacturing readiness to commercialize under Good Manufacturing Practices (GMP) and notably the production of engineering and validation batches. In addition, the Company continued to follow patients over the long term in the REFLECT Phase III clinical trial of LUMEVOQ® in the treatment of Leber Hereditary Optic Neuropathy. GenSight Biologics also continued to build up its commercial infrastructure and prepare for a possible launch of LUMEVOQ® in Europe.

In addition, the Company continued the PIONEER Phase I/II trial of GS030 in the treatment of Retinitis Pigmentosa.

In February 2023, the Company received the €8.0 million Tranche A of the €35 million loan with the European Investment Bank (EIB). As of March 31, 2023, the Company has sufficient net working capital to meet its financial obligations until June 2023.

The Company is currently reviewing the impact of the current situation on the existing financing and is taking additional measures aimed at significantly reducing its operating cash burn in 2023, while actively discussing financing and strategic options including M&A opportunities.

Number of outstanding shares

As of March 31, 2023, GenSight Biologics' number of outstanding shares was 46,335,591 ordinary shares.

2023 Annual General Meeting

GenSight Biologics is postponing its Annual General Meeting initially scheduled on May 16, 2023. A new date will be provided soon.

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About GenSight Biologics

GenSight Biologics S.A. is a clinical-stage biopharma company focused on developing and commercializing innovative gene therapies for retinal neurodegenerative diseases and central nervous system disorders. GenSight Biologics' pipeline leverages two core technology platforms, the Mitochondrial Targeting Sequence (MTS) and optogenetics, to help preserve or restore vision in patients suffering from blinding retinal diseases. GenSight Biologics' lead product candidate, LUMEVOQ® (GS010; lenadogene nolparvovec), is an investigational compound and has not been registered in any country at this stage, developed for the treatment of Leber Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease affecting primarily teens and young adults that leads to irreversible blindness. Using its gene therapy-based approach, GenSight Biologics' product candidates are designed to be administered in a single treatment to each eye by intravitreal injection to offer patients a sustainable functional visual recovery.